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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,115	04/04/2001	Gwong-Jen J. Chang	14114.0332U3	4134
46135	7590	05/16/2005	EXAMINER	
KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET SUITE 1600 PORTLAND, OR 97204			PARKIN, JEFFREY S	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/826,115	Applicant(s) CHANG, GWONG-JEN J.	
	Examiner Jeffrey S. Parkin, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17,28,32,34 and 36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17,28,32,34 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>021705</u> . | 6) <input type="checkbox"/> Other: _____ |

JD

Serial No.: 09/826,115
Applicant: Chang, G.-J.

Docket No.: 14114.0332U3
Filing Date: 04/04/01

Detailed Office Action

37 C.F.R. § 1.114

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicants' submission filed on 17 February, 2005, has been entered.

Status of the Claims

Claims 1-9, 14, 28, 32, 34, and 36 were amended in the amendment accompanying the RCE filing. Claims 1-17, 28, 32, 34, and 36 are pending and under examination in the instant application.

Information Disclosure Statement

The information disclosure statement filed 17 February, 2005, has been placed in the application file and the information referred to therein has been considered as indicated.

35 U.S.C. § 112, Second Paragraph

Claims 1-17, 28, 32, 34, and 36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as

their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims have been amended to recite an "engineered Japanese Encephalitis Virus (JEV) **signal sequence**" which is vague and indefinite since it fails to set forth any of the salient structural/functional characteristics of the modified signal sequence. What type of modifications have been made to the signal sequence? What is the coding potential of this sequence? Absent further clarification, the metes and bounds of the patent protection desired can not be ascertained.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-17, 28, 32, 34, and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yasui *et al.* (1990) in view of Kochel *et al.* (2002) and Ivy *et al.* (2000). As noted *supra*, the claims are vague and indefinite in their recitation of an "engineered" JEV signal sequence. Since both the

disclosure and claims fail to set provide a clear definition for this term, the examiner is reasonably interpreting it to simply mean any signal sequence that has been manipulated through standard molecular biology techniques (i.e., PCR amplification, cloning, etc.).

As previously set forth, Yasui and colleagues describe the preparation of recombinant baculovirus and vaccinia virus expression vectors encoding the prM, E, and NS1 proteins of the Japanese encephalitis virus (JEV). Expression cassettes were prepared comprising signal sequences and the respective genes under the control of various promoters. The authors reported (see Abstract, p. 663) that **"PrM and E proteins which had predictable signal sequences upstream on the N terminals were expressed with antigenically active form and molecular size the same as the authentic ones by the recombinant viruses.** However, the recombinant viruses which had no such signal sequence expressed unprocessed proteins with antigenically denatured forms. These results suggest that normal proteolytic processing is needed to construct biologically active structures of JEV structural proteins." This teaching does not disclose constructs encoding a signal sequence from a first flavivirus and a second flavivirus immunogen.

Kochel and associates describe the preparation of nucleic acid dengue virus vaccines comprising a nucleic acid encoding the prM signal sequence and the envelope protein. These genes may be from the same isolate or different isolates. This teaching does not disclose the utilization of a JEV prM signal sequence or signal and antigen sequences from non-DEN coding regions.

Ivy and colleagues describe the preparation of nucleic acid constructs comprising a first nucleotide sequence encoding a signal sequence and a second nucleotide sequence encoding the E

antigen of any given flavivirus (e.g., dengue, JEV, TBE, YFV, WNV, or SEV). The signal sequence may consist of either the htPA_L leader sequence or the prM leader sequence.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare an expression cassette encoding the prM signal sequence and a flavivirus immunogen (e.g., Env) as taught by Yasui et al. (1990), and to substitute immunogenic sequences from other flaviviruses, as suggested by Kochel et al. (2002) and Ivy et al. (2000), since this expression cassette would provide a facile means for inducing immune responses against the flavivirus of interest.

Response to Arguments

Applicant again traverses and submits that the references relied upon fail teach or suggest all of the claimed limitations. This argument is clearly not persuasive. The claims are simply directed toward a transcriptional unit encoding a first flavivirus structural protein signal sequence and a second flavivirus antigen. The prior art clearly provides flavivirus signal sequences and immunogens. Transcriptional units capable of encoding said proteins were also present in the prior art. Multivalent vaccine constructs were also provided. Thus, all of the claimed components were readily available in the prior art. There was sufficient motivation to combine them to arrive at the claimed invention since this would provide a facile means for inducing immune responses against different flaviviruses. Accordingly, the rejection is proper and hereby maintained.

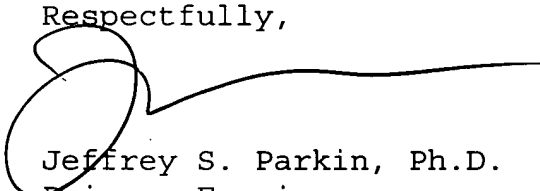
Correspondence

Any inquiry concerning this communication should be directed

to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

11 May, 2005